Secretary manages the Revolving Fund for Potable Waters in Puerto Rico, which receives grants assigned by the EPA and the federal government.

In adopting the amendments by reference, is not under the obligation to hold public hearings prior to the enactment of said rules, nor comply with any other provision of the Administrative Act. However, he shall comply with the requisite of disclosure and publication established in the Administrative Act, whenever the amendments to the federal regulations substantially affect the General Regulation.

Hoping that the aspects discussed above will be helpful, I remain,

Cordially yours,

Anabelle Rodríguez
Secretary of Justice

SECTION VII

LT2ESWTR Appendices

- Watershed and Source Water Annex
- Administrative Order 2002-364-02
- Protocol to Approve Alternative Approach to UV Reactor Validation Testing

Watershed and Source Water Assessment Process Annex

The Watershed and Source Water Assessment Process Annex will be incorporated as part of the source component of the Puerto Rico's Department of Health (PRDOH) approved Sanitary Survey Form to comply with §141.711(d) of the LT2ESWTR.

This requirement establishes that the state must assess whether significant changes have occurred in the watershed after the system conducted source water monitoring for bin classification that could lead to increase contamination of the source water by *Cryptosporidium*. In cases where a significant change has occurred, the system must take the corrective measures or additional treatment and appropriate follow-up actions specified by PRDOH.

PRDOH will first require that corrective measures be taken to address the source of contamination. Where this is not feasible or not successful, PRDOH may reclassify, in a case-by-case basis, the system into a higher treatment bin. If a system is reclassify as the result of a sanitary survey, PRDOH will report the reclassification to EPA as requires by §142.15.

This Annex discusses the three components of the watershed and source water assessment process: preparing for the sanitary survey, conducting the survey, and determining follow-up action.

Preparation for the Survey

The state or state-approved surveyor should review or address the following items before conducting a sanitary survey of a watershed:

- The state source water delineation and assessment for the watershed.
- Water system drawings and design information.
- Water quality violation history.
- Previous sanitary survey reports.
- Complaints received by local, state and federal agencies regarding water quality.
- Updates from local, state, or federal regulatory agencies regarding their monitoring of permitted discharges within the relevant watershed(s) (e.g., National Pollutant Discharge Elimination System (NPDES) and Total Maximum Daily Loads (TMDL) programs).

For systems that had received the 0.5-log *Cryptosporidium* removal credit for watershed control under the LT2ESWTR, the surveyor should also review the following information:

- The system's watershed control plan.
- The annual watershed control program status reports submitted by the system, where applicable.

Potential changes in the watershed or source water conditions that are identified from these references should then be evaluated during the survey. The surveyor should take specific equipment (e.g., cameras/camcorders, sampling/analysis equipment, and GPS devices) to document the status of potential threats to water quality.

Evaluation during the Survey

The following recommendations address several issues that should be considered when evaluating watersheds:

- Review the effectiveness of the watershed control program to date. (For example, have water quality monitoring results indicated a change in water quality?).
- Identify new significant actual or potential sources of *Cryptosporidium.*
- Verify and re-evaluate the applicability of the area of influence, potential and existing sources of Cryptosporidium, monitoring locations and results, and the implementation of control measures.
- Verify that the system has control and practices such control over watershed areas and activities as described in the watershed protection plan.
- Confirm that public access is properly restricted from areas identified in the watershed control plan. Review the means by which the system monitors and enforces restrictions.
- Confirm that fencing and signs have not been vandalized or removed.
- Identify any significant hydrological changes in the watershed that could affect Cryptosporidium loading.
- Inspect the intake structure and identify any modifications to its location or design.

The surveyor should evaluate the elements of the watershed control plan that require on-going efforts by the system during the survey and assess whether the system is regularly evaluating the effectiveness of its watershed control program (if one has been implemented).

Follow-up action

The following changes within the watershed will require immediate corrective measures by the systems:

- Inadequate implementation of the best management practices.
- NPDES permit violations at wastewater treatment plants, confined animal feedlot operations, etc.
- Lack of a current emergency response plan.
- Accidental or illegal waste discharges and spills.

Other changes may not result in immediate impacts, but may still warrant corrective measures to minimize long-term impacts:

- New NPDES permits or changes in existing NPDES permits that involve increased loading of contaminants.
- Changes in land use patterns.
- Changes in agricultural cropping, chemical application or irrigations practices.
- Unattended soil erosion.
- Changes in other non-point discharge source activities (e.g., grazing, manure application, commercial or residential development).
- Stream or riverbed modifications.

In all cases, PRDOH will indicate the system the required timeframe for a response, the required action for the response, and the consequences of failing to respond. The PRDOH have the authority to require corrective measures, and enforce them through Administrative Order AO No. 2002-364-02.

Commonwealth of Puerto Rico
Department of Health

COMMONWEALTH OF PUERTO RICO
DEPARTMENT OF HEALTH
OFFICE OF THE SECRETARY

August 5, 2002

Public Water System
Owner and/or Operator

RE: Administrative Order 2002-364-02
Order to establish requirements for action plans in response to sanitary surveys.

Public Water System Owner and/or Operator:

Act No. 5, approved on July 21, 1977, known as the Act to Protect the Purity of the Drinking Water in the Commonwealth of Puerto Rico, authorize the Secretary of Health to promulgate and enforce the necessary regulations to protect the purity of the drinking water supply in Puerto Rico and to protect the health of the people served by those systems as well. In May 1980, the Environmental Protection Agency (EPA) granted the Puerto Rico Department of Health (PRDOH) primacy for all existing national primary drinking water regulations in Puerto Rico.

EPA has promulgated the Interim Enhance Surface Water Treatment Rule (IESWTR), which requires states to conduct sanitary surveys for all PWSs using surface water or ground water under the direct influence of surface water (GWUDI) as a source.

To this extent, the PRDOH in its ministerial role to watch over the health of the Puerto Rican people, and in accordance with the provisions in Act No. 5 and the drinking water regulation, order and require that:

1. Sanitary surveys shall be conducted for all systems using surface water or ground water under the direct influence of surface water (GWUDI)[1] as a source in compliance with §142.16(b)(3) of the IESWTR:

[1] Subpart H systems: PWSs using surface water or ground water under the direct influence of surface water (GWUDI).

a. Sanitary surveys will be conducted to all systems regardless of the population the PWS serves[2];
b. Sanitary surveys will be conducted to all systems no less frequently than every three (3) years for community water systems (CWS) and every five (5) years for noncommunity water systems (NCWS), as established in §142.16 (b)(3)(i);
c. A CWS determined to have outstanding performance based on previous sanitary surveys will be eligible to conduct successive sanitary surveys at a reduced frequency (no less than five years intervals). A CWS will be considered to have outstanding performance depending on conclusive special conditions in a case-by-case basis;
d. Sanitary surveys conducted must address all eight (8) elements as described in §142.16 (b)(3)(i)(A) through (H):
    - The eight (8) sanitary survey elements are: source; treatment; distribution system, finish water storage; pumps, pump facilities, and controls; monitoring and reporting and data verification; system management and operation; operator compliance with state requirements.

2. All Public Water Systems (PWSs) must respond in writing to the significant deficiencies outlined in the sanitary survey report. PRDOH will consider as a significant deficiency any defect in a system's operation, maintenance, or administration, as well as any defect, failure or malfunction of any system component, that determines to cause, or have the potential to cause, imminent risk to health or that could affect the reliable delivery of safe drinking water:
    a. PRDOH will notify the system in writing the significant deficiencies found after conducting a sanitary survey;
    b. The system must respond in writing to PRDOH within 45 calendar days after receipt of the sanitary survey report, as established in §142.16(b)(1)(ii);
    c. The system must submit PRDOH an action plan to assure it will respond to the significant deficiencies outlined in the sanitary survey report, as established in §142.16(b)(1)(ii);
    d. The action plan must indicate how and on what schedule the system will address the significant deficiencies noted in the survey, as established in §142.16(b)(1)(ii).
3. All Public Water Systems (PWSs) must take the necessary steps to address the significant deficiencies identified in the sanitary survey report:

[2] Systems that serves 10,000 or more people must conduct sanitary surveys beginning January 1, 2002.

a. PRDOH will notify the system the approval or disapproval of the action plan in writing after its submittal.
b. The system must comply with the approved action plan schedule to assure it will take the necessary steps to address the significant deficiencies identified in the sanitary survey report, as established in §142.16(b)(1)(iii);
c. Those deficiencies that represent imminent risk to health must be notify to the system owner and/or operator for its immediate corrective action. The timeframe required for the correction will depend on the finding;

4. PRDOH must review the disinfection profile as part of the sanitary survey for systems that are required to comply with the profiling requirements in §141.172.
   a. The system must have the disinfection profile available for review as established in §142.16(b)(3)(iv).

All actions which willfully violates any of the requirements previously described shall be subject to administrative and/or legal enforcement actions, as well as penalties in accordance with the applicable rules and laws in force.

This Order, under the power granted to the Secretary of Health on Section #5 of Act No. 5, will be in force immediately after its approval.

Cordially,

Johnny Rullán, M.D., FACPM
Secretary of Health

Cc: Mr. Carl Soderberg, EPA-CEPD
Mr. Bruce Kiselica, EPA-NY
Mr. Alfredo Casta Vélez, Aux. Secretary-DOH
Ms. Olga I. Ruvera, PWSSP Dir.-DOH
Esq. Mayra Maldonado, Legal Div. Dir.-DOH

Protocol to Approve
Alternative Approach to UV Reactor Validation Testing

The Long Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR) allow states to approve an alternative approach to validation testing as established in §141.720(d)(2)(iii).

The purpose of validation testing is to determine the operating conditions under which a UV reactor delivers the validated dose and establishes the operational set points used during reactor operations to confirm delivery of the validated dose.

Acceptance of an alternative approach should reflect EPA guidance and/or peer reviewed research and be consistent with generally accepted engineering practices for the treatment scenario under consideration. In other words, the alternative approach must assess reactor performance at least as well as the validation approach in the Rule.

To this extent, UV reactors previously validated under certain existing protocols may receive log inactivation credit. Based on the recommended validation protocol presented in Chapter 5 of EPA's *UV Disinfection Guidance Manual*, PRDOH will accept the following protocols:

- Austrian Standards ÖNORM M 5873-1 (2001) and M 5873-2 (2003)
- German Guideline DVGW W294 (2006)

This protocols define measured flow rate, UV intensity, and lamp status for a *Bacillus subtilis* RED of 40mJ/cm2, which conforms to the operating conditions required under §141.720(d)(2). PRDOH will grant 3-log *Cryptosporidium* and 3-log *Giardia* inactivation credit to UV reactors certified by these protocols.

Validation by NWRI/AwwaRF Guidelines (2003) and NSF Standard 55 (2004) will be evaluated by PRDOH on a case-by-case basis to ensure that the requirements of the Rule are met.

Alternative approaches to biodosimetry for UV reactor validation, like potential model-based approaches that use computational fluid dynamics (CFD) and experimental approaches that use microspheres are still subject of current research. PRDOH may consider these emerging methods as they continue to develop and improve in the future.

Systems must demonstrate a delivered UV dose using the results of a reactor validation test to be eligible for UV disinfection credit. The UV dose values may be found in §141.720(d)(1) and Chapter 1 of EPA's *UV Disinfection Guidance Manual.*

Thus, the systems must prepare and submit to PRDOH, at least, the following documentation prior receiving the approval of an alternative approach to UV reactor validation testing:

- Documentation for the UV reactor
- Validation Test Plan
- Validation Report

The system may use as guidance the recommendations on validation testing documentation on section 5.11 from Chapter 5 of EPA's *UV Disinfection Guidance Manual.*

PRDOH will use as guidance the recommendations on section 5.12 from Chapter 5 of EPA's *UV Disinfection Guidance Manual* for reviewing validation reports and certify that key validation criteria were met.

Copy of Sections 5.11 and 5.12, with its corresponding checklists, are part of this protocol to facilitate the system and the state personnel the use of such sections.

5.11 Documentation

Prior to validation testing, the water system should work with the manufacturers, third party reviewers, and engineers assisting with or performing validation testing to prepare the following:

- Documentation for the UV reactor
- Validation Test Plan

Once validation testing and the associated data analyses are complete, the UV reactor documentation and Validation Test Plan, along with results of validation testing, should be incorporated into a ***Validation Report***.

The next several sections provide more detailed recommendations on validation testing documentation. Water systems purchasing a pre-validated reactor will not be preparing documentation; however, Sections 5.11.1 through 5.11.3 may be useful as they review validation documentation from manufacturers and consulting engineers. State personnel may also find these sections helpful when reviewing validation reports.

5.11.1 UV Reactor Documentation

Before validation testing, the UV manufacturer should provide the testing party with documentation identifying and describing the UV equipment. Documentation should include all reactor and component information that impacts UV dose delivery and monitoring, as described in Checklist 5.1.

Checklist 5.1 UV Reactor Documentation (Page 1 of 2)

Does UV reactor documentation contain the following elements?

Yes No

General

☐ ☐ Technical description of the reactor's UV dose-monitoring strategy, including the use of sensors, signal processing, and calculations (if applicable).

☐ ☐ Dimensions and placement of all wetted components (e.g., lamps, sleeves, UV sensors, baffles, and cleaning mechanisms) within the UV reactor.

☐ ☐ A technical description of lamp placement within the sleeve.

☐ ☐ Specifications for the UV sensor port indicating all dimensions and tolerances that impact the positioning of the sensor relative to the lamps. If the UV sensor port contains a monitoring window separate from the sensor, specifications giving the window material, thickness, and UV transmittance should be provided.

Lamp specifications

☐ ☐ Technical description
☐ ☐ Lamp manufacturer and product number
☐ ☐ Electrical power rating
☐ ☐ Electrode-to-electrode length
☐ ☐ Spectral output of new and aged lamps (specified for 5 nm intervals or less over a wavelength range that includes the germicidal range of 250 – 280 nm and the response range of the UV sensors)
☐ ☐ Mercury content
☐ ☐ Envelope diameter

Lamp sleeve specifications

☐ ☐ Technical description including sleeve dimensions
☐ ☐ Material
☐ ☐ UV transmittance (at 254 nm for LP and LPHO lamps, and at 200 – 300 nm for MP lamps with germicidal sensors)

Specifications for the reference and the duty UV sensors

☐ ☐ Manufacturer and product number
☐ ☐ Technical description including external dimensions
☐ ☐ Data and calculations showing how the total measurement uncertainty of the UV sensor is derived from the individual sensor properties. (See Table D.1 for an example of the calculation of UV sensor measurement uncertainty from the uncertainty that arises due to each UV sensor property.)

Checklist 5.1 UV Reactor Documentation (Page 2 of 2)

Does UV reactor documentation contain the following elements?

Yes	No	
Sensor measurement properties		
☐	☐	Working range
☐	☐	Spectral and angular response
☐	☐	Linearity
☐	☐	Calibration factor
☐	☐	Temperature stability
☐	☐	Long-term stability
Installation and operation documentation:		
☐	☐	Flow rate, head loss, and pressure rating of the reactor
☐	☐	Assembly and installation instructions
☐	☐	Electrical requirements, including required line frequency, voltage, amperage, and power
☐	☐	Operation and maintenance manuals that include cleaning procedures, required spare parts, and safety requirements. Safety requirements should include information on electrical lockouts, eye and skin protection from UV light, safe handling of lamps, and mercury cleanup recommendations in the event of lamp breakage.

5.11.2 Validation Test Plan

A validation test plan should document the key components of UV reactor testing. Recommended components of a validation test plan are provided in Checklist 5.2. This list is not meant to be all-inclusive; engineers should document any factors they believe are important for validation testing in their Validation Test Plan.

Checklist 5.2 Key Elements of the Validation Test Plan (Page 1 of 1)

Does the validation test plan contain the following elements?

Yes	No	
☐	☐	Purpose of Validation Testing. General description of why the tests are being done and how the data will be used.
☐	☐	Roles and Responsibilities. Key personnel overseeing and performing the full-scale reactor testing and collimated beam testing, including their qualifications. This section should include contact names and telephone numbers.
☐	☐	Locations and Schedule. Location for conducting full-scale reactor testing and collimated beam testing. Planned schedule for conducting the tests and performing the data analyses.
☐	☐	Challenge Microorganism Specifications. Specifications for the challenge microorganism to be used during validation that include the protocols required for growth and enumeration, the expected UV dose-response, and suitability for use in validation testing.
☐	☐	Plan for state review (if applicable).

Design of the Biodosimetry Test Stand/On-site Testing Facilities

☐	☐	Inlet/outlet piping design, including backflow prevention
☐	☐	Mixing
☐	☐	Sample ports
☐	☐	Pumps
☐	☐	Additives (Material Safety Data Sheets for UV-adsorbing chemical, quenching agent)

Collimated Beam Testing Apparatus

☐	☐	Lamp type
☐	☐	Collimating tube aperture
☐	☐	Distance from light source to sample surface
☐	☐	Radiometer make and model

Monitoring Equipment Specifications and Verification of Equipment Accuracy for the following:

☐	☐	Flow meters
☐	☐	UVT analyzers (if used)
☐	☐	UV Spectrophotometers
☐	☐	Power measurement
☐	☐	UV sensors
☐	☐	Radiometer make, model, and calibration certificates

Experimental Test Conditions including, but not limited to:

☐	☐	Number of tests, UVT, flow rate, lamp power, and lamp status for each test condition
☐	☐	Lamp fouling factor, use of new or aged lamps
☐	☐	Influent concentration of challenge microorganisms for each test condition
☐	☐	QA/QC Plan

5.11.3 Validation Report

The validation report should provide detailed documentation of all validation testing results. The report should also include all elements of the Validation Test Plan and a summary of the field-verified UV reactor properties.

EPA recommends that the report begin with an executive summary with key information that can be used by states and water systems to assess inactivation credit for the target pathogen(s). The executive summary should include, at a minimum,

- The validated dose or range of validated doses,
- The log credit achieved for the potential target pathogens by the UV reactor, and
- Validated operating conditions (i.e., flow rate, UVT if the Calculated Dose approach is used).

If the UV Intensity Setpoint approach is used, the executive summary should provide the UV intensity setpoint (or setpoints) for the validated dose. If the reactor uses the Calculated Dose Approach as its dose monitoring strategy, the dose-monitoring equation should be provided.

In addition to the items listed above, the executive summary should include the following:

- A brief description of the validated reactor,
- The assumed fouling/aging factors for the reactor and indication if new or aged lamps were used during validation testing,
- A summary of the validation test conditions, including but not limited to the flow rate, UVT, and lamp power for each test condition,
- Key validation test results used to derive the dose, including but not limited to the RED values for each test condition, the UV dose-monitoring equation from collimated beam testing, and the VF,
- A summary of QA/QC checks and results, including UV sensor and radiometer reference checks,
- A description of the validation facilities,
- The organizations conducting the validation test, and
- Names and credentials of the individuals/organizations providing third party oversight.

Recommended contents for the detailed validation report are listed in Checklist 5.3. Note that these recommendations are not intended to be all-inclusive. Engineers should document any test characteristics or outcomes they believe are important in the Validation Report.

Checklist 5.3 Key Elements of the Validation Report (Page 1 of 1)

Does your validation report contain the following elements?

Yes No

General

☐ ☐ Detailed reactor documentation (see Checklist 5.1), including drawings and serial numbers, and procedures used to verify reactor properties.

☐ ☐ Validation test plan (either a summary of key elements, or the test plan can be attached to the validation report along with documentation of any deviations to the original test plan)

Full-scale reactor testing results, with detailed results for each test condition evaluated. Data should include, but are not limited to:

☐ ☐ Flow rate

☐ ☐ Measured UV intensity

☐ ☐ UVT

☐ ☐ Lamp power

☐ ☐ Lamp statuses

☐ ☐ Inlet and outlet concentrations of the challenge microorganism

Collimated beam testing results, including detailed results for each collimated beam test used to create the UV dose-response equation:

☐ ☐ Volume and depth of microbial suspension

☐ ☐ UV Absorption of the microbial suspension

☐ ☐ Irradiance measurement before and after each irradiation

☐ ☐ Petri factor calculations and results

☐ ☐ Calculations for UV dose

☐ ☐ Derivation of the UV dose-response equation, including statistical methods and confidence intervals (i.e., calculation of U_{DR})

QA/QC Checks:

☐ ☐ Challenge microorganism QA/QC, including blanks, controls, and stability analyses

☐ ☐ Measurement uncertainty of the radiometer, date of most recent calibration, results of reference checks

☐ ☐ Measurement uncertainty of UV sensors and results of reference checks

☐ ☐ Measurement uncertainty of the flow meter, UV spectrophotometer, and any other measurement equipment used during full-scale testing

Calculation of the validated dose, log inactivation credit, and validated operating conditions:

☐ ☐ RED for each test condition

☐ ☐ Calculation of the VF

☐ ☐ Setpoints if the reactor uses the UV Intensity Setpoint Approach

☐ ☐ Dose-monitoring equation if the reactor uses the Calculated Dose Approach

☐ ☐ Log inactivation credit for target pathogens (e.g., *Cryptosporidium*, *Giardia*, and viruses)

☐ ☐ Validated operating conditions (e.g., flow rate, lamp status, UVT)

5.12 Guidelines for Reviewing Validation Reports

State engineers and water systems purchasing pre-validated reactors should review the validation report to confirm the following:

- Validation testing meets the minimum regulatory requirements as summarized in Table 5.1.
- EPA's recommended validation protocol was followed and any deviations from the protocol are adequately justified.
- Validated doses achieved by the UV equipment meet or exceed the target pathogen log inactivation desired.
- QA/QC criteria were met during validation testing.

Checklist 5.4 summarizes the QA/QC recommendations presented throughout this chapter and in Appendix C. If a QA/QC plan was prepared prior to validation, reviewers should request a copy of the plan and make sure it is consistent with industry standards.

Checklist 5.5 contains key elements that should be verified by state or water system personnel when reviewing validation reports. States and systems should keep documentation that these key validation criteria were met.

Checklist 5.4 Review for Quality Assurance/Quality Control (Page 1 of 1)

Yes No

Uncertainty in Measurement Equipment (See Section 5.5 and C.2.2 for more information)

☐ ☐ **Flow Meter:** Is the measurement uncertainty < 5 percent?

☐ ☐ **UV Spectrophotometer:** Is the measurement uncertainty ≤ 10 percent?

☐ ☐ **UV Sensors:** Did duty sensors operate within 10 percent of the average of two or more reference sensors? If not, was uncertainty in sensor measurement incorporated into the VF?

☐ ☐ **Radiometer:** (for collimated beam testing only). Do lamp output measurements vary by no more than 5 percent over exposure time? Was the accuracy of the radiometer verified with another radiometer?

QA/QC of Microbial Samples (See Section 5.6.4 for more information)

☐ ☐ **Reactor controls:** For influent/effluent samples taken with the UV reactor lamps turned off, does the change in log concentration correspond to a change in RED that is within the measurement error of the minimum RED measured during validation (typically ≤ 3 %)?

☐ ☐ **Reactor blanks:** For DAILY influent/effluent samples taken with NO challenge microorganisms injected, are the measured concentrations of the challenge microorganism negligible?

☐ ☐ **Trip Controls:** For an UNTESTED sample bottle of challenge microorganism stock solution that travels with tested samples between the laboratory and the reactor, is the change in the log concentration of the challenge microorganism within the measurement error. (I.e., the change in concentration over the test run should be negligible. This is typically on the order of 3 to 5%.)

☐ ☐ **Method Blanks:** For sterilized reagent grade put through the challenge microorganism assay procedure, is the challenge microorganism concentration non-detectable?

☐ ☐ **Stability Samples**: For influent/effluent samples at low and high UVT, are the challenge microorganism concentrations within 5 percent of each other?

Uncertainty in Collimated Beam Testing Data (See Appendix C for more information)

☐ ☐ Do the uncertainties in the terms in the UV dose calculation meet the following criteria:

- Depth of suspension (d) ≤ 10 percent
- Incidence irradiance (E_s) ≤ 8 percent
- Petri factor (P_f) ≤ 5 percent
- L/(d + L) ≤ 1 percent
- Time (t) ≤ 5 percent
- $(1 - 10^{-ad})/ad$ ≤ 5 percent

☐ ☐ Is the **uncertainty in dose-response** (U_{DR}), as calculated using equation C.6, less than or equal to 30 percent? If not, was U_{DR} incorporated into the VF?

Checklist 5.5 Review for Key Validation Report Elements (Page 1 of 2)

Yes	No	
☐	☐	Does the validation testing meet QA/QC criteria (see Checklist 5.4)?
☐	☐	For full-scale testing, does the mixing and location of sample ports follow recommendations provided in Sections 5.4.3 and 5.4.4, respectively?
☐	☐	If the reactor was validated off-site, do inlet/outlet piping conditions at the water treatment plant result in a UV dose-delivery that is **the same or greater than** the UV dose delivery at the off-site testing facility? (See Section 3.6 for recommended inlet/outlet piping configurations and Section D.6 for considerations for CFD modeling.)
☐	☐	Were collimated beam tests and full-scale reactor tests performed on the same day for a given test condition and using the same stock solution of challenge microorganisms? (See Section 5.7 for experimental testing guidelines.)
☐	☐	Is the UV sensitivity of the challenge microorganism and the overall shape of the UV dose-response curve consistent with the expected inactivation behavior for that challenge microorganism? See Appendix A of this manual for published UV dose-response curves for MS2 and *B. subtilis*.
☐	☐	Does the validation test design account for lamp fouling and aging, minimum UVT, and maximum flow rate expected to occur at the water treatment plant? (See Section 5.6 for recommended test design.)
		For UV Reactors Using MP Lamps
☐	☐	Is the UV reactor equipped with a germicidal sensor? New UV reactors should have germicidal sensors. If an installed reactor uses an MP lamp and a non-germicidal sensor, is a polychromatic bias factor incorporated into the derivation of the VF? (See Section D.4.3 for guidance on the polychromatic bias factor.)
☐	☐	Was validation testing conducted using a challenge microorganism other than MS2 or *B. Subtilis*? If yes, was the need for a correction factor assessed and was that factor applied based on the outcome? (See Sections 5.3 and D.4.1 for more information)
		For UV Reactors Using the UV Intensity Setpoint Approach
☐	☐	Were the minimum test conditions performed as specified in Section 5.6.1?
☐	☐	Is the UV intensity setpoint low enough to account for combined conditions of minimum UVT and maximum lamp fouling/aging at the water treatment plant (See Section 5.6.1 for guidance)
☐	☐	Was the **minimum RED** selected for calculating the validated dose? (See Section 5.8.1 for additional guidance.)
☐	☐	Does the VF calculation include both the B_{RED} and U_{SP}? (See Section 5.9 for additional guidance.)

Checklist 5.5 Review for Key Validation Report Elements (Page 2 of 2)

Yes	No	
For UV Reactors Using the UV Intensity Setpoint Approach (continued)		
☐	☐	If U_S and/or U_{DR} did not meet the QA/QC criteria, were they also included in the VF calculation?
☐	☐	Is the validated dose greater than or equal to the required dose for the water system's target pathogen and log inactivation level?
For UV Reactors Using the Calculated Dose Approach		
☐	☐	Was the minimum number of test conditions evaluated as specified in Section 5.6.2?
☐	☐	Was the empirical equation developed using standard statistical methods (e.g., multivariate linear regression)? (See Section 5.8.2 for additional guidance.)
☐	☐	Does the validation report include an analysis of goodness of fit and bias for the dose-monitoring equation? (See 5.8.2 for additional guidance.)
☐	☐	Does the VF calculation include both the B_{RED} and U_{IN}? (See 5.9.)
☐	☐	If U_S and/or U_{DR} did not meet the QA/QC criteria, were they also included in the VF calculation?
☐	☐	For the range of UVT values and flow rates expected to occur at the water system, is the validated dose greater than or equal to the required dose for the system's target pathogen and log inactivation?

Commonwealth of Puerto Rico
Department of Health
Public Water Supply Supervision Program

Stage 2 Disinfectants and Disinfection Byproducts Rule Primacy Revision Application Package

Stage 2 DBPR

December 2007

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Stage 2 DBPR

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SECTION

1

State Primacy Revision Checklist

State Primacy Revision Checklist

Stage 2 DBPR

Program Elements		Revision to State Program	EPA Findings / Comments
§ 141.2	Definitions	Adopted by Reference	
§ 142.10 (b)(6)(iii)	Right of entry	^	
§ 142.10 (b)(6)(iv)	Authority to require records	^	
§ 142.10 (b)(6)(v)	Authority to require public notification	^	
§ 142.10 (b)(6)(vi)	Authority to assess civil and criminal penalties	^	
§ 142.10 (b)(6)(vii)	Authority to require CCRs	^	
§ 142.10 (c)	Maintenance of records	^	
§142.10 (d)	Variance/Exemption conditions (if applicable)*	^	
§142.10 (e)	Emergency plans	^	
§142.10 (f)	Administrative Penalty Authority**	^	
* Regulation published in August 14, 1998 *Federal Register.*			
** Requirement from the 1996 Amendments. Regulations published in the April 28, 1998 *Federal Register.*			
^ Appropriate documentation of these provisions are in AGO of August 21, 2000, included in this package.			

SECTION

11

Text of the State's Regulation

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CERTIFICATE OF TRANSLATOR

I certify that the foregoing is a true and exact translation of the Spanish version of Article Number II - Drinking Water of the Drinking Water Section of the General Bylaws of Environmental Health, provided to Crespo & Rodríguez, Inc.

Witness my hand this 12th day of June, 2002, in San Juan, Puerto Rico.

Crespo & Rodríguez, Inc.

Luis A. Ruiz Javier
Translator

ARTICLE II: DRINKING WATER

Section 1.00 PUBLIC SYSTEMS OF DRINKING WATER

1.01 Requisites on Primary Standards.

1. All existing water systems and all those which will be established after the date of approval of these Regulations should comply with the requisites on primary contaminants.

2. The drinking water primary standards in Puerto Rico should be regulated in accordance with Title 40, Part 141 of the Federal Code Regulations, as amended.

1.02 Implementation of the Regulations on Primary Standards.

1. The implementations of the standards on drinking water primary contaminants in Puerto Rico will be subject to Title 40, Part 142 of the CFR, as amended.

1.03 Requisites on Secondary Standards.

1. The drinking water secondary contaminants will be regulated in accordance with Title 40, Part 143 of the CFR, as amended.

1.04 Revolving Fund.

1. Prior to commencement of operation, the Secretary is authorized to require that the drinking water systems, existing systems or new systems commencing to operate on or after October 1, 1999, be these comunal or noncomunal nontransient, to comply with Sections 1419 and 1420 of the Federal Safe Water Act, as amended; as well as with the provisions of Title 40 of the Federal Code Regulations aplicable to the primacy of the Drinking Water Program of the Department; and with federal regulations of the Revolving Fund Program and its Sub-programs. The Secretary is also authorized to order

discontinuance of the operation of the drinking water systems which do not comply with these requisites.

2. The water systems to be built the Revolving Fund Program should comply with Sections 1452, 1419 and 1420 of the Federal Safe Drinking Water Act, as amended; also they should comply with the federal guides or provisions of the Federal Code Regulations, as applicable, as well as with the procedures established by the Department under said program.

1.05 Variations and Exemptions.

1. The Department may grant variations and exemptions from specified provisions in accordance with Title 40, Part 1414 of the CFR as provided by the Federal Safe Drinking Water Act of December 16, 1976, as amended.

1.06 Additional Requisites.

1. The provisions of Section 1 of this Article should in no way be construed as a limitation of the authority of the Secretary to establish additional requisites or more stringent standards to those provided on Federal Drinking Water Act of 1974, as it may be amended, and Federal Code Regulations, as may be amended, with the purpose of safeguarding public health.

Section 2.00 BOTTLED WATER

2.01 Requisites for Processing and Bottling.

1. All plants engaged in bottling water for human comsumption in Puerto Rico should comply the water processing and bottling requisites provided on Title 21, Part 129 of the Federal Code Regulations, as amended.

2.02 Specific Requisites for Bottled Water.

1. Water bottled in Puerto Rico and all imported bottled water should comply with the quality standards and specific requisites for bottled water establish in Title 21, Part 165.110 of the CFR, as amended.

2.03 Labelling of Containers for Water and Water Products.

1. Water bottled in Puerto Rico and all bottled water imported from plants located outside of Puerto Rico should comply with the provisions of Title 2, Part 101 of the CFR, as amended.

2.04 Sound Manufacturing Practices.

1. The provisions for sound manufacturing practices contained in Title 21, Part 110 of the CFR will apply to the water bottling plants in Puerto Rico.

2.05 Bottling Plants Outside of Puerto Rico.

1. Water from all water bottling plants located outside of Puerto Rico, sold displayed, distributed, offered for sale or donation in Puerto Rico should comply with the water standards established in these Regulations.

2.06 Quality Control.

1. It will be the responsability of the operator to make sure that sample representative of the water bottled by the plant be analized by a certified laboratory, following the frequency and for the parameters specified on Title 21, Part 129, Section 129.80, Sub-part E of the CFR.

SECTION

III

Stage 2 DBPR Primacy Revision Crosswalk

SUMMARY OF FEDERAL REQUIREMENT	FEDERAL CITATION	STATE CITATION (DOCUMENT TITLE, PAGE NUMBER, SECTION/PARAGRAPH)	DIFFERENT FROM FED. REQUIREMENT? (EXPLAIN ON SEPARATE SHEET)
SUBPART A - GENERAL			
'141.2 DEFINITIONS			
Combined distribution system	'141.2	Adopted by Reference	
Consecutive system	'141.2	Adopted by Reference	
Dual sample set	'141.2	Adopted by Reference	
Finished water	'141.2	Adopted by Reference	
GAC10	'141.2	Adopted by Reference	
GAC20	'141.2	Adopted by Reference	
Locational running annual average	'141.2	Adopted by Reference	
Wholesale system	'141.2	Adopted by Reference	
SUBPART B - MAXIMUM CONTAMINANT LEVELS			
§ 141.12 MAXIMUM CONTAMINANT LEVELS FOR TOTAL TRIHALOMETHANES.			
Section 141.12 is removed and reserved.	§ 141.12	Adopted by Reference	
SUBPART C - MONITORING AND ANALYTICAL REQUIREMENTS			
§ 141.30 TOTAL TRIHALOMETHANES SAMPLING, ANALYTICAL AND OTHER REQUIREMENTS.			
Section 141.30 is removed.	§ 141.30	Adopted by Reference	